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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,917	03/16/2004	Gertrud Hotten	2923-609	2179
6449 7590 05/30/2008 ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005				
EXAMINER ROMEO, DAVID S				
ART UNIT 1647		PAPER NUMBER		
NOTIFICATION DATE 05/30/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-PAT-Email@rfem.com

Office Action Summary

Application No.

10/800,917

Applicant(s)

HOTTEN ET AL.

Examiner

David S. Romeo

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-15 is/are pending in the application.
- 4a) Of the above claim(s) 8, 9, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10, 11, 14 and 15 is/are rejected.
- 7) ☒ Claim(s) 6 and 7 is/are objected to.
- 8) ☒ Claim(s) 6-15 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 6–15 are pending.

Applicant's election of group I, claims 6–7 and 10–15, drawn to methods of treatment comprising administering MP52, in the reply filed on 01/09/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8–9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 01/09/2007.

Applicant's election of the species treatment of skin in the reply filed on 05/18/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 12–13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/18/2007.

Maintained formal matters, objections, and/or rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 14 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Celeste (5,658,882) as evidenced by Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

Applicants argue that the claims are supported by the priority document filed on 08/10/1993. Applicants' arguments have been fully considered but they are not persuasive. None of the foreign priority documents appears to contemplate the induction of angiogenesis. Therefore Celeste qualifies as prior art.

5 **New Formal Matters, Objections and/or Rejections**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Terminal Disclaimer

10 The terminal disclaimer filed on 04/09/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on U. S. Application Nos. 10/472,389 and 11/080,494 has been reviewed and is accepted. The terminal disclaimer has been recorded.

15 The terminal disclaimer filed on 04/09/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U. S. Patent No. 6,120,760 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

20 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

25 Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

30 The claims are directed to or encompass a method of treatment comprising administering a protein with the amino acid sequence of SEQ ID NO: 13. Although the specification shows a comparison between the amino acid sequence of MP-52 and several members of the BMP protein family starting with the first of the seven conserved cysteine residues (SEQ ID NO: 13)

(Figure 1), the specification does not describe or contemplate the claimed methods of treatment with SEQ ID NO: 13. Therefore, this limitation is new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

- 5 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which
10 applicant regards as the invention.

Claims 10, 11, 14 and 15 are directed to or encompass "biologically functional parts." It is unclear which biological function is intended. Consequently, it is unclear which parts are intended. The metes and bounds are not clearly set forth.

Claim Rejections - 35 USC § 102

- 15 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- 20 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 11, 14 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Celeste (U. S. Patent No. 5,658,882) as evidenced by Yamashita (Exp Cell Res. 1997 Aug 25;235(1):218-26).

- 25 A 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

- (A) Prove the primary reference contains an "enabled disclosure;"
- (B) Explain the meaning of a term used in the primary reference; or
- (C) Show that a characteristic not disclosed in the reference is inherent.

- 30 MPEP § 2131.01.

The claims are directed to or encompass a method of treatment comprising administering a protein with the amino acid sequence of SEQ ID NO: 13. Although the specification shows a comparison between the amino acid sequence of MP-52 and several members of the BMP protein family starting with the first of the seven conserved cysteine residues (SEQ ID NO: 13)

(Figure 1), the specification does not describe or contemplate the claimed methods of treatment with SEQ ID NO: 13. Therefore, this limitation is new matter. Therefore, the present application is not entitled to the benefit of the filing dates of any of the earlier filed applications to which priority is claimed..

Celeste teaches purified human MP52 proteins which contain the amino acid sequence represented by amino acids #1 to #120 of SEQ ID NO: 4. It is also expected that the amino acid sequence from amino acids #17 or #19 to #119 or #120 of SEQ ID NO: 4 will retain activity. Thus, the DNA sequence from nucleotides #845, #893 or #899 to #1201 or #1204 are expected to encode active proteins. See column 7, full paragraph 2. Amino acids 19 to 120 of Celeste's SEQ ID NO: 4 are identical to SEQ ID NO: 13, as indicated below:

```
US-08-333-576C-4
; Sequence 4, Application US/08333576C
; Patent No. 6027919
; INFORMATION FOR SEQ ID NO: 4:
;   SEQUENCE CHARACTERISTICS:
;     LENGTH: 120 amino acids
;     TYPE: amino acid
;     TOPOLOGY: linear
;   MOLECULE TYPE: protein
US-08-333-576C-4
```

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Query Match          100.0%;   Score 568;   DB 3;   Length 120;
Best Local Similarity 100.0%;   Pred. No. 1.2e-54;
Matches 102;   Conservative 0;   Mismatches 0;   Indels 0;   Gaps 0;

Qy      1  CSRKALHVNFKDMGWDDWIIAPLEYEAFHCEGLCEFFLRSHLEPTNHAVIQTLNMSMDPE 60
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      19 CSRKALHVNFKDMGWDDWIIAPLEYEAFHCEGLCEFFLRSHLEPTNHAVIQTLNMSMDPE 78

Qy      61 STPTCCVPTRLSPISILFIDSANHVVKQYEDMNVVESCGR 102
        ||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db      79 STPTCCVPTRLSPISILFIDSANHVVKQYEDMNVVESCGR 120.
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Celeste also teaches a pharmaceutical composition comprising MP52 (column 11, full paragraph 2) and biocompatible, porous matrix materials that can be biologically degraded, wherein the protein is contained on and/or in a natural or synthetically prepared matrix material (column 12, line 40, through column 13, line 22).

Celeste also discloses compositions comprising MP52 that are used for skin repair (paragraph bridging columns 11-12).

Celeste discloses a method for inducing tendon/ligament-like tissue formation in a patient in need of same comprising administering to said patient an effective amount of a composition

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comprising a protein which exhibits the ability to induce formation of tendon/ligament-like tissue, said protein having amino acids 19-120 of SEQ ID NO: 4 (column 3, full paragraph 3). Celeste's method further comprises administering a matrix, carrier, diluent and/or filler along with said protein having an amino acid sequence shown in SEQ ID NO: 4 (paragraph bridging columns 12-13 through paragraph bridging columns 13-14).

The compositions are administered along with a matrix, carrier, diluent and/or filler (paragraph bridging columns 12-13 through paragraph bridging columns 13-14).

The induction of angiogenesis is inherent to the Celeste's method, as evidenced by Yamashita (Abstract).

Therefore, Celeste discloses a method for treating damage to skin or for inducing angiogenesis comprising administering the polypeptide of SEQ ID NO: 13 to a patient in need of such treatment.

Conclusion

Claims 6 and 7 are objected to as being directed to non-elected species, there being no allowable generic or linking claim.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, MANJUNATH RAO, CAN BE REACHED AT (571)272-0939.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE [HTTP://PAIR-DIRECT.USPTO.GOV](http://PAIR-DIRECT.USPTO.GOV). CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID S ROMEO/
PRIMARY EXAMINER, ART UNIT 1647